

TO: Dr. Carl Dieffenbach, Director, Division of AIDS, National Institute of Allergy and Infectious Disease

CC: Dr. Sharon Nachman, Chair, International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Dr. James McIntyre, Vice Chair, International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Dr. Daniel Kuritzkes, Chair, AIDS Clinical Trials Group

Dr. Judith Currier, Vice Chair, AIDS Clinical Trials Group

15 December 2015

Letter to support the establishment of a tuberculosis registry for pregnant women

Dear Dr. Dieffenbach,

As advocates for communities affected by tuberculosis (TB), we have a special interest in ensuring the ability of neglected populations to participate in and benefit from research. This interest necessarily extends to pregnant women, who despite a potentially favorable risk-benefit are systematically excluded from TB research. As a result, clinicians are forced to use old and sometimes new regimens in pregnant women with TB, without guidance on dose adjustments, safety, or efficacy. We are writing to encourage the National Institutes of Health (NIH) to establish a registry for pregnant women with TB—in the absence of clinical trials data, this initiative is critical to informing the safe treatment of pregnant women with TB.

We urgently need research to guide the prevention of progression of latent TB infection and the treatment of active TB disease in pregnant women, including those co-infected with HIV, and acknowledge the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and AIDS Clinical Trials Group's (ACTG) pursuit of research to answer these important questions. A registry for pregnant women with TB is a complementary initiative that will contribute to the work of the IMPAACT network and ACTG and help inform the safe treatment of pregnant women with TB.

The Antiretroviral Pregnancy Registry (APR), established in 1989, is one of the largest pregnancy registries in the world. The APR prospectively monitors potential birth defects in infants exposed to antiretrovirals in utero, provides early warning of major teratogenicity, and helps estimate risk of birth defects. Data collection is through voluntary enrollment by healthcare providers of pregnant women exposed to antiretrovirals. While the APR is sponsored and maintained by pharma, there are few companies investing in TB drug research. In fact, the NIH is the leading funder of TB research overall, and has been since Treatment Action Group (TAG) first began tracking funding for TB research and development in 2005. It is unlikely that a registry for pregnant women with TB will be established without public funding and the NIH's leadership.

The NIH has been an important champion of TB research. We urge the NIH to continue to invest in this neglected and vulnerable population and, as part of that investment, to establish a registry for pregnant women with TB.

To further discuss the essentiality of this initiative to informing the safe treatment and prevention of TB in pregnant women and their children with members of the Global TB Community Advisory Board (TB CAB), Community Research Advisors Group (CRAG), Community Partners (CP), TAG, and the Women's HIV Research Collaborative please contact me by e-mail at Lindsay.McKenna@treatmentactiongroup.org or phone at (212) 253-7922.

Sincerely,

A handwritten signature in cursive script that reads "Lindsay McKenna".

Lindsay McKenna, MPH
TB/HIV Project Officer
Treatment Action Group

On behalf of:

Global TB Community Advisory Board (TB CAB)
Community Partners (CP)
Community Research Advisors Group (CRAG)
Treatment Action Group (TAG)
Women's HIV Research Collaborative